**UNITED STATES DISTRICT COURT**

**NORTHERN DISTRICT OF OHIO**

**EASTERN DIVISION**

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| IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION | MDL 2804 |
| | Case No. 17-md-2804 |
| *This document relates to:* | Hon. Dan Aaron Polster |
| Track One Cases | |

# PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE TESTIMONY OF DAVID KESSLER, MD AND MATTHEW PERRI

July 31, 2019

***In re National Prescription Opiate Litigation*: MDL 2804**
**Summary Sheet of Concise Issues Raised**

**Opposition Name:** Plaintiffs' Memorandum in Opposition to Defendants' Motion to Exclude the Testimony of David Kessler, MD and Matthew Perri

**Opposing Parties:** Plaintiffs Summit County and Cuyahoga County

Defendants' motion to exclude the testimony of Dr. David Kessler and Professor Matthew Perri is wholly lacking in merit and should be denied. The testimony at issue is well-grounded in Dr. Kessler and Prof. Perri's expertise, helpful to the factfinder, and admissible in its entirety.

First, contrary to Defendants' arguments, Dr. Kessler's and Dr. Perri's use of corporate documents is appropriate and does not constitute improper narrative or invade the province of the jury. Not only are these types of documents commonly relied upon by experts, but it is well-established that Courts regularly allow experts to discuss documents that form the basis of their opinions. Second, Dr. Kessler's and Prof. Perri's opinions do not speculate about the knowledge, intent, motivation, or state of mind of the manufacturers. Experts like Dr. Kessler and Prof. Perri are free to testify as to a defendant's knowledge when that knowledge is demonstrated in the record.

Defendants' challenge to Prof. Perri's methodology misconstrues Prof. Perri's work and expert opinions. Prof. Perri's case study methodology and his application of the principles of marketing fit the facts and law of this case and give rise to admissible opinions. Defendants are likewise mistaken that Dr. Kessler offers improper legal opinions. Courts allow a qualified expert to offer testimony on whether a party complied with FDA regulations, as well as the relevant duty of care under state law. Plaintiffs anticipate offering Dr. Kessler to address areas about which Dr. Kessler has been routinely permitted to testify.

Finally, Dr. Kessler does not seek to offer undisclosed opinions regarding Johnson & Johnson/Janssen subsidiaries' Noramco and Tasmanian Alkaloids role in supplying oxycodone. Dr. Kessler's testimony shows that he was responding to questions with facts he was aware of from his review of internal company documents, which are cited on his list of reliance materials.

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## INTRODUCTION

Defendants seek to exclude in their entirety the opinions of Plaintiffs' regulatory expert Dr. David A. Kessler and Plaintiffs' pharmaceutical marketing expert Prof. Matthew Perri III. Linking together two experts with different expertise and backgrounds, and reports of different focus and scope, Defendants argue that each of them offers improper narrative and speculation regarding Defendants' intent or state of mind. In both cases, however, the experts offer opinions based on what Defendants' internal documents actually say. It is hardly improper to opine that a Defendant "knew" something when its own internal documents show that it did know. In the case of Prof. Perri, Defendants also purport to attack his methodology, but Prof. Perri is not a scientific expert. Rather, he is an expert in pharmaceutical marketing – a subject he teaches at the university level -- with particular knowledge and expertise about the standards and practices of that industry. His opinions, grounded in this specialized discipline are proper and admissible. Finally, Defendants seek to exclude Prof. Perri's opinions on the ground that they are based on assumptions with which Defendants do not agree. But it is entirely proper for an expert to give testimony based on assumptions; Plaintiffs have the opportunity to, and will, connect Prof. Perri's testimony to the facts of this case by proving the truth of what he assumed.

As for Dr. Kessler, a well-respected, even renowned, former head of the federal Food and Drug Administration ("FDA"), Defendants haul out the time-worn canard that Dr. Kessler is merely offering improper legal opinions. Courts have delineated time and again the proper scope of testimony that a regulatory expert may offer. Dr. Kessler's opinions fall squarely within the bounds of what is permissible. Finally, Defendants seek to exclude testimony they elicited at Dr. Kessler's deposition, which they contend are undisclosed opinions. As explained below, they are not.

Despite the narrowness of their challenges, Defendants make no attempt to limit the scope of their motion or to exclude only the portions of testimony they contend are improper. But it makes no difference: the testimony at issue here is well-grounded in both the witnesses' respective

expertise and the factual record, helpful to the factfinder, and admissible in its entirety. Defendants' motion is wholly lacking in merit and should be denied.

## THE EXPERTS AND THEIR REPORTS

### Dr. Kessler

Dr. David Kessler received his MD degree from Harvard and his JD from the University of Chicago in 1978 and 1979, respectively. He has had special training in pharmacoepidemiology at Johns Hopkins Hospital. He is the former head of the FDA under the administrations of Presidents George H. W. Bush and Bill Clinton. He has taught food and drug law at Columbia University School of Law and has testified many times before the United States Congress on food, drug, and consumer protection issues under federal and state law. He has published numerous articles in legal, medical and scientific journal on the federal regulation of food, drugs, and medical device, including articles on drug promotion and marketing practices and on addiction. In the private sector, he has advised companies on the standards and duties of care in the pharmaceutical and medical device industry.

After extensive review and analysis of the branded and unbranded promotional activities of each Manufacturer Defendant, he concludes that they departed from FDA standards by understating the risks and overstating the benefits of prescription opioids, and that this misleading promotion contributed to a shift in the practice of medicine with regard to the use of opioids in the treatment of pain. This change in the practice of medicine led to an increase in opioid prescriptions and an increase in inappropriate use of opioids, which in turn increased the risk of opioid abuse and contributed to a public health crisis. In Dr. Kessler's opinion, because the promotional violations discussed in his report are serious, corrective promotion and medical education that disseminates truthful, non-misleading, and complete corrective messaging about the violations discussed above to the audiences that received the violative promotion is warranted.

**Professor Perri**

Matthew Perri III, BS Pharm, PHD, RPh, is a professor of pharmaceutical marketing, He earned his Ph.D. with a dual concentration in Pharmacy and Marketing; he also holds a Bachelor of Science in Pharmacy. Prof. Perri has worked in and around the pharmaceutical industry for nearly 40 years. He wrote "the book" on pharmaceutical marketing. He has also published multiple articles in peer-reviewed journals and book chapters on pharmaceutical marketing, and has conducted extensive original research on pharmaceutical marketing. Prof. Perri does marketing analyses of marketing campaigns and regularly assesses the effectiveness of marketing campaigns.[1]

In his report, Prof. Perri explains what pharmaceutical marketing is, how it differs from other marketing, and what basic standards companies that market prescription opioids should follow. He also examined documents provided by the Defendant and, based on those documents, offers opinions about the Defendants' marketing strategies with respect to prescription opioids, how those strategies were implemented, what Defendants' marketing messages were and how they were disseminated, as well as the effectiveness of Defendants' marketing.

## ARGUMENT

### I. DR. KESSLER'S AND PROF. PERRI'S OPINIONS DO NOT SPECULATE ABOUT THE KNOWLEDGE, INTENT, MOTIVATION, ETHICS, OR STATE OF MIND OF THE MANUFACTURERS.

#### A. Dr. Kessler's and Prof. Perri's Use of Corporate Documents Is Proper and Does Not Invade the Province of the Jury.

Dr. Kessler will offer testimony regarding the regulatory standards governing marketing by a pharmaceutical company in Defendants' position, and testify that Defendants breached that standard of care based upon his understanding derived from the plethora of internal documents he reviewed and analyzed. Dr. Kessler employed the same methodology as he did as the former Commissioner of the FDA, and he has immense experience and knowledge regarding FDA

[1] Report of Matthew Perri, III, BS Pharm, Ph.D., RPh, Dkt. #2000-19 at 1-3 (¶¶2-12); see also Perri Rep., Dkt. #2000-19 at 6 (¶ 20), Schedule 1: Curriculum Vitae, Matthew Perri III, January 30, 2019, Schedule 2: Perri Prior Testimony and Depositions.

regulations. Defendants would nonetheless have this Court believe that Dr. Kessler cannot opine on Defendants' actions, as presented in the contemporaneous internal documents he reviewed, in relation to those governing regulations.

Similarly, Prof. Perri has reviewed Defendants' internal documents in order to assess the marketing strategies reflected in them. Using his expertise in marketing generally and in pharmaceutical marketing in particular, Prof. Perri is able to recognize particular marketing strategies and to assess the marketing messages Plaintiffs used.[2] In a case in which allegations of improper marketing play such a large role, Prof. Perri's assessment of Defendants' marketing documents provides useful context to the fact-finder. In both cases, Defendants' argument to exclude this type of testimony is completely without merit.

Not only are these types of documents commonly relied upon by experts, but it is well-established that Courts regularly allow experts to discuss documents that form the basis of their opinions. *See, e.g., In re Actos Prods. Liab. Litig.,* MDL No. 6:11-md-2299, 2014 WL 4364832 at *9-10 (W.D. La. Sept. 2, 2014) (noting that Dr. Kessler's trial testimony was based in part on his review of a plethora of documents); *Sanchez v. Boston Sci. Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *4 (S.D. W. Va. Sept. 29, 2014) (noting that "an expert may testify about his or her review of internal documents solely for the purpose of explaining the basis for his or her opinions); *In re Flonase Antitrust Litig.*, 884 F. Supp. 2d 184, 192-93 (E.D. Pa. 2012) (permitting expert to use internal documents to opine on information that was available to manufacturer regarding FDA practice and policy as to approval of drug application); *In re Fosamax Products Liab. Litig.,* 1:06–MD–1789 (JFK), 645 F.Supp.2d 164, 192 (S.D.N.Y. 2009) (permitting expert to comment on documents and exhibits in the context of "explaining the regulatory context in which they were created, defining any

[2] Prof. Perri does not opine about the truth or falsity of Defendants' marketing. His focus, rather, is on the strategies reflecting in the marketing and in the internal documents related to marketing.

complex or specialized terminology, or drawing inferences that would not be apparent without the benefit of experience of specialized knowledge).

Defendants attempt to cast doubt on Dr. Kessler's opinions by arguing that he cherry-picked documents.[3] Nothing could be further from the truth. As evidenced from his report, testimony, and materials relied on, Dr. Kessler carefully conducted an extensive review of publications, internal documents, product labels, clinical studies, depositions, exhibits, and more before forming his opinions.[4] In fact, Dr. Kessler's analysis of documents is consistent with the same methodology he employed as the former Commissioner of the FDA.

Defendants also argue that Dr. Kessler and Prof. Perri provide improper narrative testimony.[5] This argument is baseless. Both experts fully comply with Fed. R. Civ. P. 26 by summarizing the material, studies, and other facts relied on in reaching their conclusions, and courts have repeatedly denied requests to preclude such testimony, including specifically as to Dr. Kessler. *See, e.g.*, *In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Prod. Liab. Litig. ("In re Yasmin")*, 09-md-02100, 2011 WL 6302287, at *13 (S.D. Ill. Dec. 16, 2011) ("[T]he Court has broad discretion over the mode and order of examining witnesses and presenting evidence and may allow testimony in narrative form at trial if the Court finds that it would [be] helpful to the jury."); *see also In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig.*, 11-MD-2244, 2016 WL 9560113, at *8 (N.D.Tex. Oct. 3, 2016) ("The admission of Dr. Abramson's alleged speculation and narrative testimony, however, is not properly the subject of this Court's gatekeeping function under *Daubert*. It implicates this Court's discretion over the presentation of evidence at trial and should be taken up there."); *In re Actos Prods. Liab. Litig.*, No. 12-cv-00064, 2014 WL 120973, at *10 (W.D. La. Jan. 10,

[3] *See* Memorandum in Support of Defendants' Motion to Exclude the Testimony of David A. Kessler, M.D. and Matthew Perri, III BS Pharm, Ph.D., RPh ("Defs.' Mot."), Dkt. #1786-3 at 10.

[4] *See* Report of David A. Kessler, M.D., Dkt. #2000-8.

[5] *See* Defs.' Mot., Dkt. #1786-3 at 10.

2014) ("The objection that testimony is 'narrative' is an objection as to form, foundation, or responsiveness, and must be presented at trial..."); *see also Wells v. Allergan*, No. CIV-12-973-C, 2013 WL 7208337, at *3 (W.D. Okla. 2013) (same); *In re Bard IVC Filters Prod. Liab. Litig.*, No. MDL 15-02641, 2017 WL 6523833, at *8 (D. Ariz. Dec. 21, 2017) (whether narrative testimony "will be proper during any part of Dr. Kessler's testimony must be determined at trial").

There is nothing improper about either Dr. Kessler or Prof. Perri discussing the documents they relied upon in reaching their conclusions. *See, e.g., In re Yasmin*, 2011 WL 6302287, at *13 (" '[T]here is [. . .] nothing particularly unusual, or incorrect, in a procedure of letting a witness relate pertinent information in a narrative form as long as it stays within the bounds of pertinency and materiality.' "); *In re Bard IVC Filters*, 2017 WL 6523833, at *8 ("Furthermore, the Court notes that narrative testimony is appropriate in some circumstances.") (citing *In re Yasmin*, 2011 WL 6302287, at *13); *Wells*, 2013 WL 7208337, at *3 ("To the extent the facts relied on by [expert] in forming her opinions are relevant and not cumulative, [she] may include them in her testimony."); *In re: Tylenol (Acetaminophen) Mktg., Sales Practices, & Prod. Liab. Litig.*, No. 2:12-CV-07263, 2016 WL 4538621, at *8 (E.D. Pa. Aug. 31, 2016) ("A narrative may be admissible, however, if an expert's explanation of complicated facts can help a jury better understand them."); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 2017 WL 1836443, at *15 ("AbbVie contends that Dr. Kessler's testimony amounts to an improper factual narrative with a 'spin' that requires no specialized knowledge. It contends that this amounts to improper advocacy that would invade the 'fact-finding province of the jury.' The Court disagrees. Dr. Kessler's testimony will assist the jury in determining its ultimate conclusions, and it presents no danger of invading the jury's province.").

At its core, Defendants' argument that the "jury is capable of reading the Manufacturers' documents and drawing conclusions"[6] is nothing more than the familiar trial objection that "the

[6] *See* Defs.' Mot., Dkt. #1786-3 at 10.

document speaks for itself." Such general objections are more properly addressed by the Court at trial, in the context of specific documents and expert testimony, not by way of a *Daubert* motion. *See, e.g., In re Actos (Pioglitazone) Prods. Liab. Litig.*, 2014 WL 120973, at *10 (W.D. La. Jan. 10, 2014); *Johnson v. Wyeth LLC*, No. CV 10-02690-PHX-FJM, 2012 WL 1204081, at *3 (D. Ariz. Apr. 11, 2012) ("Objections to narrative testimony, however, are best made at trial"); *Lea v. Wyeth LLC*, Case 1:03-cv-01339-MAC (E.D. Tex. Oct. 6, 2011) (defendant's motion to exclude "narrative" testimony denied "[s]hould [the experts] become witnesses that merely read documents to the jury, as Defendants suggest, an objections should be lodged at trial that the documents speak for themselves."); *see also In re E. I. Du Pont De Nemours & Co. C-8 Pers. Injury Litig.*, 345 F. Supp. 3d 920, 926–27 (S.D. Ohio 2015); *see also In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings,* No. 14 C 1748, 2017 WL 1836443, at *15 (N.D. Ill. May 8, 2017) (rejecting argument that expert was merely regurgitating evidence, court held that "to the extent [the expert] is summarizing voluminous records and materials, as appears to be the case, this aspect of his testimony is properly admitted under Federal Rule of Evidence 1006 as well as Rule 702 in the sense that he is identifying what he, given his background and expertise, considers to be the most salient aspects of those voluminous materials."); *In re Laurel Valley Oil Co.*, No. 05-64330, 2015 WL 4555579, at *6 (Bankr. N.D. Ohio July 28, 2015) (expert testimony including recitation of facts admissible because it "does not consist solely of factual regurgitation or 'common sense' observations, but instead combines expert knowledge with a factual underpinning to arrive at valid expert testimony"). For these reasons, the Court should deny Defendants' motion and instead reserve any rulings on specific objections for trial, in light of the usefulness, relevance, and admissibility of the testimony offered.

**B. Dr. Kessler's and Prof. Perri's Opinions Are Not Speculative.**

Contrary to Defendants' suggestions, the Federal Rules of Evidence do not categorically preclude expert testimony concerning "the knowledge, motives, or intent of individuals or

organizations."[7] Rather, Rule 702 bars an expert's *speculation* as to those matters. *See, e.g.*, *Drake v. Allergan, Inc.*, No. 13-cv-234, 2014 WL 5392995, at *6 (D. Vt. Oct. 23, 2014) (expert may not "speculate about other individual's or entity's motives, knowledge, or intent"); *see also Wells v. Allergan, Inc.*, No. CIV-12-973-C, 2013 WL 7208221, at *2 (W.D. Okla. 2013) (prohibiting expert speculation about intent or state of mind *but permitting testimony* about facts from which the jury could infer intent).

Experts like Dr. Kessler and Prof. Perri are free to testify as to a defendant's knowledge when that knowledge is demonstrated in the record. *See In re Tylenol Mktg Sales Practices & Prod. Liab. Litig.*, 13-md-02436, 2016 WL 4039329, at *5 (E.D. Pa. July 28, 2016); *see also Shults v. Int'l Flavors & Fragrances, Inc.*, No. C 11-4077, 2014 WL 12603223, at *3 (N.D. Iowa July 18. 2014) ("To the extent that an expert adequately demonstrates a basis for an opinion about what the defendants knew or should have known from such information that was within the defendants' possession, then such an opinion may be admissible at trial, if the proper foundation is laid."). While Dr. Kessler and Prof. Perri may not "guess" as to what Defendants or the FDA knew, they may reply on *documents* to explain the information that was available to Defendants and their employees at the time. They are free to testify to factors or conditions that may have motivated a party to take (or not take) a certain action, so long as such testimony does not *speculate* definitively as to the party's motive. *See, e.g., In re Tylenol (Acetaminophen) Mktg., Sales Practices & Prod. Liab. Litig.*, 181 F. Supp. 3d 278, 296 (E.D. Pa. 2016) ("This does not mean, however, that the plaintiff's experts cannot offer evidence that could allow a jury to infer what the defendants' corporate state of mind would be. This is entirely appropriate."); *DePaepe v. Gen. Motors Corp.*, 141 F.3d 715, 720 (7th Cir. 1998) (Expert "could give an opinion as an engineer that reducing the padding saved a particular amount of money; he might testify as an engineer that GM's explanation for the decision was not sound (from which the jury

[7] Defs.' Mot., Dkt. #1786-3 at 2.

*might infer* that money was the real reason) ...") (emphasis added). The case upon which Defendants themselves rely, *Wells*,[8] demonstrates that Dr. Kessler and Prof. Perri may testify about facts from which the jury can infer intent, as they have done here. *Wells v. Allergan, Inc.*, 2013 WL 7208221, at *2-3.

Indeed, testimony regarding a party's "intent" is not improper if that intent is clearly identifiable from the record. *In re Levaquin*, No. 08-md-1943, 2011 WL 6888533 at *2 (D. Minn. Dec. 29, 2011) (permitting defense regulatory expert to testify regarding the FDA's intent where "clearly indicated in public documents"); *In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 479-80 (S.D.N.Y. 2016) (same as to plaintiffs" regulatory expert's testimony on the FDA's or the defendant's intent; allowing testimony on "motives, intent, state of mind" where "set forth in documents or grounded in specific, objectively knowable facts."); *see also In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prod. Liab. Litig.*, 2016 WL 9560113, at *7 (expert may apply "specialized knowledge in the discipline of marketing, including the areas of marketing codes, regulations, and guidelines, to analyze voluminous specific marketing representations made by Defendants, and this testimony is helpful to the factfinder" because this would be an "application of … expertise to documents and their contents, not speculation as to [Defendant's] state of mind").

Such testimony by Dr. Kessler has been admitted by several courts, including with regards to a defendant's marketing strategy. *Actos Prods. Liab. Litig.*, No. 12-cv-00064, 2014 WL 120973, at *16 (W.D. La. Jan. 10, 2014) (Each of the statements "in which the Defendants complain that Dr. Kessler implies something about Takeda's intent…is supported within his report by sometimes-lengthy discussion of the data, information, and sources upon which these statements are founded."); *see also In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 2017 WL 1836443, at *15 (allowing testimony by Dr. Kessler in which he evaluated defendant's

[8] Defs.' Mot., Dkt. #1786-3 at 3, 11, 13.

"marketing materials and internal memoranda to assess whether and to what extent it was targeting patients with certain conditions" and which "offers a framework by which the jury can assess what [defendant] intended via its marketing"); *In re Yasmin* 2011 WL 6302287, at *14 ("Dr. Kessler's experience in enforcing the FDCA, working with DDMAC, and advising drug companies provides sufficient experience and expertise to understand defendant's marketing scheme and to opine as to its economic purpose. Dr. Kessler's report provides extensive support for his opinions surrounding this matter.").

In contrast, the cases cited by Defendants are inapposite or distinguishable. In *Wells*, the court did not discuss any specific testimony offered by Dr. Kessler, but summarily agreed with the defendant in principle that Dr. Kessler could not engage in mind-reading of the defendant or FDA. 2013 WL 7208337, at *2. The court noted, however, that while Dr. Kessler could not testify as to intent, he could "testify as to facts from which jury can infer intent." *Id. In re Prograf Antitrust Litig.*, is similar: there the court devoted one sentence to finding that Dr. Kessler could not testify as to discerning the defendant's state of mind, without describing any of his testimony. No. 11-MD-02242, 2014 WL 7641156 (D. Mass. Dec. 23, 2014). Defendants' other cases are even less on point.[9]

Moreover, and significantly, the examples cited by Defendants come from the *testimony* of Dr, Kessler and Prof. Perri, not from their reports. In effect, Defendants solicited testimony from the witnesses for the purpose of excluding it, taking it out of context to get the sound bites they

[9] In *In re Fosamax Prods. Liab. Litig.*, 645 F.Supp.2d 164, 192 (S.D.N.Y. July 27, 2009), the court found the expert's report "replete with…conjecture" in reading minds, which is not the case with Dr. Kessler's testimony, nor do Defendants even so suggest. In *In re Diet Drugs*, 2000 WL 876900 at *9 (E.D. Pa. 2000), the court found that the experts' "particular scientific disciplines…[did] not include knowledge or even experience in the manner in which corporations and the pharmaceutical marketplace react, behave or think regarding their non-scientific goals of maintaining a profit-making organization that is subject to rules, regulations, standards, customs and practices among competitors and influenced by shareholder or public opinion." Neither expert had FDA or pharmaceutical experience, unlike Dr. Kessler, who has both. In *Raley v. Hyundai Motor Co.*, No. CIV-08-0376-HE, 2010 WL 528420, at *6 (W.D. Okla. Feb. 11, 2010), the expert testified that the only reason the defendant didn't use better glass was to save money at the expense of human suffering, but he admitted he had no basis for any opinion as what the company knew or didn't know at the time, and had no evidence that the decision was based on cost.. In *U.S. v. Organon*, 2015 WL 10002943 at *4 (D. Mass. 2015), the expert opined as to what regulators would have reasonably believed with no explanation of how his experience led to those conclusions.

need to portray these experts as doing something they did not do. The opinions Dr. Kessler and Prof. Perri seek to offer are those set forth in their report; even Defendants, with all of their editing, cannot find examples there of improper speculation about intent.

Nor does the testimony Defendants identify support their argument. For example, the context for Dr. Kessler's statement at his deposition "that the company knew," cited by Defendants without any reference to the subject matter, shows he was responding to a question about what FDA "understood about the patient populations to whom OxyContin was being marketed to in 2001,"[10] and in fact suggested that the DDMAC letters cited and analyzed in his report, which he brought to his deposition and which Defendants received from FDA, be consulted for what FDA "was on the record saying:"[11] Dr. Kessler responded that the four warning letters the company received from the FDA "probably reflect[] at least some extent what the company knew."[12] In other words, Dr. Kessler was simply asserting that the letters showed FDA's statements on the issue, and that Defendants had the information contained in the letters because they received them. His testimony was based entirely on facts in the record. Indeed, it is hard to imagine a less speculative assertion. *See*, e.g., *In re Tylenol Mktg Sales Practices & Prod. Liab. Litig.*, 2016 WL 4039329, at *5.

Similarly, Dr. Kessler's deposition testimony that "what wasn't disclosed to the agency was the game plan to significantly increase the dose beyond what American medicine was using"[13] is based upon Purdue's marketing plans, cited in his report, that refer to exactly that that, plans to market higher doses.[14] The same applies to his testimony regarding Purdue's "explicit strategy" to remove the stigma of morphine.[15] This is in fact explicit in many Purdue documents that are in the

[10] David A. Kessler, M.D., Dep. (04/25/19), Dkt. # 1963-15 at 68 L22 to 69 L1.

[11] *Id.* at 69 L20-21.

[12] *Id.* at 69 L17-24.

[13] Kessler Dep., Dkt. # 1963-15 at 325 L20-23.

[14] Kessler Rep., Dkt. #2000-8 at 73-74 (¶¶143-144 n.215-216), 79(¶148.3 n.235), 86(¶153.5 n.257).

[15] Kessler Dep., Dkt. # 1963-15 at 335 L20-24; Kessler Rep., Dkt. #2000-8 at 42-46 (¶¶102-104.3).

record and cited in Dr. Kessler's report.[16] These opinions were offered by Dr. Kessler in response to Purdue counsel's rote recitations of statements in the OxyContin label and a Dear Healthcare Provider Letter accompanying the label during his deposition,[17] with Dr. Kessler pointing out that the problem as to dosing and stigma was not for the most part what was in the label, but what was in Purdue's marketing.[18] This testimony is based on documents in the record and falls squarely within Dr. Kessler's expertise. *See In re Yasmin*, 2011 WL 6302287, at *14.

Finally, the context for Dr. Kessler's statement at his deposition regarding "FDA's understanding" of Defendants' marketing of their opioids for indications beyond the label, and FDA's understanding of the extent of abuse of Defendants' opioids, was a discussion of what FDA knew and did not know about same based on Dr. Kessler's own firsthand experience with opioids while at FDA in the 1990s, and on Purdue call notes in the record that he quoted from at the deposition, which showed that Purdue representatives marketed OxyContin for mild pain and reported its abuse and "street value."[19] Thus this testimony was also properly based on sources in Dr. Kessler's experience and in the documentary record.

The two examples used by Defendants with respect to Prof. Perri are similarly inaccurate. First, Defendants point to Prof. Perri's response to a question by defense counsel at his deposition counsel regarding "Purdue's intent with respect to development of OxyContin."[20] This line of questioning was not about Purdue's corporate intent, but Prof. Perri's use of the OxyContin launch plan as one data point considered and interpreted by Prof. Perri as part of his methodology. And indeed, nothing in Prof. Perri's report on this issue touches on the question of speculation about intent.

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[16] Kessler Rep., Dkt. #2000-8 at 43 (n.106-110), 44(n.111), 45(n.113-115), 46 (n.116-117).

[17] *See* Kessler Dep., Dkt. # 1963-15 at 320 L6 to 324 L15, 333 L24 to 335 L12.

[18] Kessler Dep., Dkt. # 1963-15 at 335 L20 to 336 L2 ("The issue is not the label; the issue is the promotion.")

[19] Kessler Dep., Dkt. # 1963-15 at 291 L22 to 295 L21.

[20] Matthew Perri, III, BS Pharm, Ph.D., RPh, Dep. (04/23/19), Dkt. #1969-7 at 163 L3-14.

Finally, Defendants extract a phrase from Prof. Perri's extended response to the question of "What are you providing that any other person in this room or on the jury couldn't come to their own conclusion about?" to suggest that Prof. Perri is offering evidence about Defendants' intent. When reading Prof. Perri's response in full, it is clear that Prof. Perri's opinion is not an opinion about intent, but rather about marketing theory. [21] His point is that what he brings is sufficient expertise in marketing theory to explain why marketers use particular techniques and how they work. Again, Defendants are unable to point to anything in Prof. Perri's report that suggests he intends to offer speculation about intent.

## II. PROF. PERRI'S TESTIMONY IS RELIABLE, RELEVANT, AND ADMISSIBLE

### A. Defendants Misconstrue Prof. Perri's Work and Expert Opinions in this Matter.

Defendants purport to challenge Prof. Perri's methodology, but address their arguments to a straw man, rather than to the methodology Prof. Perri actually used. In his report, Prof. Perri used a case study methodology grounded in marketing principles to systematically review Defendants' marketing conduct.[22] Experts in his field routinely use the case study methodology, and Prof. Perri regularly performs, reviews, and writes about case studies. He teaches graduate and undergraduate courses on pharmaceutical marketing and research methods wherein he and his students use case studies every day. Prof. Perri is also hired to perform case studies outside of the classroom and outside of litigation. Case study methodology is a proper method for Prof. Perri to analyze defendants' marketing campaigns.

To start his case study, Prof. Perri was asked to assess the significance, if any, of Defendants' marketing related to prescription opioids.[23] Supplemental questions included: (1) What is pharmaceutical marketing? (2) What are the basic standards or rules, if any, that the companies

[21] *Id.* at 187 L13 to 189 L20.

[22] Perri Rep., #2000-19 at 4-6 (¶ ¶13-19).

[23] *Id.* at 5 (¶17).

which market prescription opioids should follow? (3) What were the Defendants' marketing strategies with respect to prescription opioids? (4) How were marketing strategies implemented and marketing messages disseminated by Defendants with respect to prescription opioids? (5) What were Defendants' messages? (6) What happened as a result of any opioid marketing?[24] Prof. Perri started with these questions and, using the case study methodology, he then posed propositions in response to the questions that were either supported or negated by data points (documents and testimony) from the case.

Notably, in a case study methodology, an expert does not base any conclusion on one data point. Each conclusion is based on multiple data points that support or negate a proposition. Only when enough data is present can a conclusion be made and reported.

Defendants do not challenge Prof. Perri's use of the case study methodology. Indeed, the words "case study" do not even appear in Defendants submission. Instead, Defendants either deliberately misrepresent Prof. Perri's methodology or they themselves do not understand how pharmaceutical marketing works. This is exactly why a pharmaceutical marketing expert is needed to help the trier of fact understand pharmaceutical marketing and synthesize Defendants' voluminous marketing materials.

*1. The Principles of Marketing Are Not a Methodology.*

The principles of marketing are fundamental truths about marketing that guide all effective marketing behavior and are, therefore, the theoretical underpinning of the marketing techniques that are explained throughout Prof. Perri's report. The principles of marketing set forth in Prof. Perri's case study methodology help define the marketing methods used by Defendants and why those methods work. As required by the case study methodology and explained throughout Prof. Perri's report, the principles of marketing were then applied to multiple data points, documents and

[24] *Id.* at 5 (¶17).

testimony from this case, in support of Prof. Perri's expert opinions. *See Terry v. McNeil-PPC, Inc. (In re Tylenol Acetaminophen Mktg.)*, No. 2:12-cv-07263, 2016 WL 807377, at *5 (E.D. Pa. Mar. 2, 2016) ("A marketing professional's review and analysis of company documents to extrapolate marketing strategies, coupled with the expert's experience and background may be enough to establish that the expert's methodology is reliable.") (collecting cases).

Prof. Perri's case study methodology used the principles of marketing because they are well known, well-established marketing principles that were proven to have generated millions of dollars for Defendants. They are not an "undefined" standard created by Prof. Perri himself, but are compiled, supported, and defined by consistently agreed-upon standards from around the world and then tested against the data points presented in this case. In fact, Prof. Perri cited the testimony of Defendants' own marketing witnesses in describing these principles.[25]

The trier of fact will need to understand the principles to understand Defendants' marketing techniques and why those techniques work. For example, the principle of "positioning" has meaning to a marketer regarding how a product is defined in the customers mind, whereas "positioning" itself does not have meaning to a lay person as a principle of marketing. Every marketer, including Defendants, has the goal of "positioning" their product in customers' minds so that when a product need arises, the customer thinks of that marketer's product, first and favorably.

This principle is important to understand when, for example, a Defendant sends an internal communication about allowing persistent incorrect perceptions about opioids and uses the word "position" in the "true marketing sense of the word." The Defendant in that example acknowledges that allowing incorrect perceptions is favorable to the marketer's goals, because Defendants themselves understand that the principle of positioning. The trier of fact, however, would not understand Defendants' use of that principle without expert guidance.

[25] Perri Rep., Dkt. #2000-19 at 18 (n. 36).

That is exactly why "positioning" is a principle of marketing tested in Prof. Perri's case study methodology. It is a fundamental truth about how and why marketing works. Multiple marketing texts define marketing principles like price, place, product, promotion, segmentation, targeting, position, and distribution and define why these principles are the foundation of marketing. These are not nebulous principles, at least not to marketers. Defendants of course know this already, because they are savvy marketers.

But the principles are not a methodology. Prof. Perri used a case study methodology to study and explain what the principles mean to Defendants' marketing. As explained throughout Prof. Perri's report, the principles are tethered to Defendants' marketing because each decision a company makes about how to communicate about its product in the marketplace is based on marketing principles such as price, place, product, promotion, segmentation, targeting, positioning, planning, implementation, and evaluation.

Prof. Perri explains not only what the principles of marketing are but also how to apply those principles to understand how and why Defendants' marketing worked, through use of a case study methodology. Defense counsel misunderstand or misconstrue what the marketing principles are and how the marketing principles were used in Prof. Perri's case study. Defendants' *Daubert* submission itself is precisely why Prof. Perri is needed to assist the trier of fact. *See Schwab v. Philip Morris USA, Inc.,* 2005 U.S. Dist. LEXIS 21610, at *13 (E.D.N.Y. Sept. 29, 2005) ("Advertising methodologies are esoteric; the average juror could be helped by an explanation of how they work and were used by defendants.").

*2. Prof. Perri's Opinions Are Not Based on an Improper Assumption*

Contrary to Defendants' submission, Prof. Perri's methodology does not "start" with an assumption that Defendants' marketing conduct was unlawful, nor is Prof. Perri offering an opinion

on lawfulness.[26] Although a portion of Prof. Perri's report does assume that the marketing was misleading, most of Prof. Perri's opinions are not in any way based on such an assumption.

Prof. Perri's report sets forth seven opinions.[27] Defendants' argument relates to only one of the seven opinions, specifically "Opinion 5: Defendants' marketing failed to adhere to industry standards in their marketing of opioids."[28] With respect to this one opinion, Prof. Perri was asked to assume – as just one data point in his case study methodology – that "Plaintiffs' expert reports rendered in this case assessed the common messages delivered by Defendants' marketing and hold the opinions that Defendants' messages were false, misleading, inaccurate, or designed to misstate the risks and benefits of Defendants' drugs."[29] Not only was this assumption not even considered with respect to any of Prof. Perri's other six primary opinions, but it was also only one data point of many with respect to Opinion 5.

As set forth in Prof. Perri's report, this one assumption plays a limited role in Prof. Perri's case study methodology and his opinion that Defendants failed to adhere to industry standards. Not only was it only one data point, but it was also consistent with other data points that were evaluated by Prof. Perri. For example, as set forth in Prof. Perri's report, there was evidence from the FDA warning letters about Defendants' false and misleading messages. Further, as a pharmacist, Prof. Perri is knowledgeable about the pharmacology of opioids and it is within his expertise to know that the pharmacology of opioids did not change, and that Defendants' messages were different from what the pharmacology supported. Prof. Perri's opinion that Defendants failed to adhere to industry standards in their marketing of opioids was based on multiple behaviors, not just an assumption he was asked to make.

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[26] Defs.' Mot., Dkt. #1786-3 at 7.

[27] Perri Rep., Dkt. #2000-19 at 7-9.

[28] Perri Rep., Dkt. #2000-19 at 8.

[29] Perri Rep., Dkt. #2000-19 at 138 (¶154).

Nor in any event does this assumption render even Opinion 5 inadmissible. Plaintiffs have repeatedly explained – and will prove at trial – why all of Defendants' opioid promotion *was* inaccurate and misleading. It is entirely proper for an expert to offer opinions based on hypotheticals and assumptions. *See* Fed. R. Evid. 703, Advisory Committee Note ("Facts or data upon which expert opinions are based may, under the rule, be derived from … the familiar hypothetical"). It is true, of course, "that expert testimony should be excluded if it relies on facts that no jury could accept, or relies on the rejection of facts that any jury would be required to accept," *Lee v. Smith & Wesson Corp.*, 760 F.3d 523, 527 (6th Cir. 2014), but Prof. Perri's testimony is based on an assumption that Plaintiffs are prepared to prove at trial is reasonable.

*3. AseraCare Did Not Exclude Prof. Perri's Case Study Methodology.*

Defendants erroneously argue that Prof. Perri's methodology ought to be excluded here because certain of his testimony was excluded in a prior case.[30] Defendants misrepresent the *AseraCare* opinion. *AseraCare* did not exclude Prof. Perri's case study methodology as unreliable, did not exclude Prof. Perri's opinion because it was a narrative, and is not a basis to exclude Prof. Perri's pharmaceutical marketing expert opinions here.

First, contrary to Defendants' argument, *AseraCare* did not exclude Prof. Perri's expert opinion because his methodology was unreliable. The issue, rather, was that Prof. Perri lacked expertise in the specific industry at issue there. Thus, the *AseraCare* Court stated, "While Prof. Perri is highly qualified in the fields of pharmacy and general healthcare marketing, Prof. Perri's credentials and methodology do not support his expert opinions regarding *AseraCare*'s business practices and marketing *in the hospice industry*." *United States v. AseraCare Inc.*, No. 2:12-CV-245-KOB, 2014 WL 6879254, at *11 (N.D. Ala. Dec. 4, 2014) (emphasis in original). "Prof. Perri has no experience *in the hospice industry* …" *Id.* at *11 (emphasis added). "Prof. Perri's opinions about

[30] Defs.' Mot., Dkt. #1786-3 at 1 ("he uses an ill-defined and generic 'principles of marketing' methodology that another federal court has excluded as unreliable"), 3 ("Other courts have prevented … Perri from offering similar narratives").

AseraCare's 'business practice' are outside his area of expertise because [he] makes no attempt to explain how his 'universal principles of marketing' methodology has any bearing on AseraCare's *hospice business objectives*." *Id.* at *12 (emphasis added). "Prof. Perri's testimony without any basis in hospice practices, could be *more* confusing to the jury and more prejudicial than probative." *Id.* (emphasis in original). Prof. Perri's expert opinion was excluded in *AseraCare* because Prof. Perri was not a hospice expert. *Id.* at *11-12. Here, by contrast, Prof. Perri is an expert specifically in the pharmaceutical industry.

Second, contrary to Defendants' argument, *AseraCare* did not exclude Prof. Perri's expert opinion because it was a narrative. The *AseraCare* opinion does not use the word narrative. The opinion states that "Prof. Perri merely recites the documentary evidence and testimony of former AseraCare employees regarding AseraCare's marketing and business practices, then makes conclusory statements about what AseraCare knew" but the context of this statement is the opinion's discussion on Prof. Perri's lack of experience *in the hospice industry*. *Id.* at 19-20. *AseraCare* does not say that Perri's case study methodology in and of itself is unreliable or excludable as an impermissible narrative. *See Terry v. McNeil-PPC, Inc. (In re Tylenol Acetaminophen Mktg.)*, No. 2:12-cv-07263, 2016 WL 807377, at *5 (E.D. Pa. Mar. 2, 2016) ("A marketing professional's review and analysis of company documents to extrapolate marketing strategies, coupled with the expert's experience and background may be enough to establish that the expert's methodology is reliable.") (collecting cases). Again, the point appears to have been that Prof. Perri's analysis of the documentary evidence would not help the fact-finder because he lacked expertise in the relevant industry.

In short, Defendants fail to present any argument or even concerns about Perri's case study methodology. Instead, Defendants' submission misconstrues or misrepresents Prof. Perri's methodology and greatly expands the holding of one prior case wherein Prof. Perri's opinions were

excluded because he lacks experience in the hospice industry. As explained in Plaintiffs' Daubert Roadmap Brief, the Sixth Circuit has held that where the expert's overall methodology was sound, "[a]ny weaknesses in his methodology will affect the weight that his opinion is given at trial, but not its threshold admissibility." *Best v. Lowe's Home Centers, Inc.*, 563 F.3d 171, 182 (6th Cir. 2009). So too is the conclusion with Prof. Perri: where Defendants do not challenge his case study methodology, any other weakness is fodder for cross-examination, not grounds for exclusion.

**B. Prof. Perri's Opinions Fit the Facts and Law of this Case and Are Admissible.**

Defendants claim that Prof. Perri's opinions do not fit Plaintiffs' theory of the case, but the entirety of this attack pertains to one portion of one sentence from Perri's 155-page report.[31] That one statement is taken from a brief summary of Defendants' marketing themes and is not one of the opinions Prof. Perri is proposing to offer.[32] *See* Perri Rept., Dkt. #2000-19 at 7-9 (setting forth opinions). Thus, Defendants pounce on a single statement that is included in Prof. Perri's disclosure of the basis for his opinions.[33] On its face, such an attack does not justify the exclusion of even one of Prof. Perri's proposed opinions, to say nothing of all of them.

The statement in question is that one of Defendants' marketing themes "includes the expansion of the indication for patients who require opioid therapy for 'more than a few days' into 'chronic use' as well as the claim that there is evidence of improved functioning in patients taking opioids for chronic pain; the omission of side-effects associated with long-term use such as hyperalgesia and sedation."[34] This is not an attack on the FDA, nor an opinion about the propriety of the FDA-approved label; it is a discussion of marketing themes. Moreover, it corresponds to the facts of the case: Defendants were successful in expanding the indication for opioid therapy and

[31] Defs.' Mot., Dkt. #1786-3 at 8.

[32] Perri Rep., Dkt. #2000-19 at 80-82 (¶134).

[33] *Id.* at 7-9.

[34] *Id.* at 80-82 (¶134).

this *was* a marketing theme, even before the indication was actually expanded.[35] In addition, Prof. Perri identifies this "theme" as including the misrepresentation that there was evidence of improved functioned in patients taking opioids for chronic paid and the omission of side-effects associated with such use. These portions of the "theme" fit *precisely* Plaintiffs' case.

## III. DEFENDANTS' REMAINING ATTACKS ON DR. KESSLER ARE UNFOUNDED

### A. Dr. Kessler Does Not Offer Improper Legal Opinions

Defendants' argument that Dr. Kessler offers impermissible legal opinions conflates two separate issues: (1) the federal regulatory framework governing manufacture, marketing, and sale of prescription drugs in this country and (2) the state and federal law of nuisance and RICO, which the fact-finder will apply to decide if Defendants are liable for the harms caused by the opioid epidemic. Contrary to Defendants' arguments, courts allow a qualified expert to offer testimony on FDA regulations, including whether a party complied with such regulations, as well as the relevant duty of care under state law. *See In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d at 467 ("Expert testimony regarding Bayer's compliance with FDA regulations therefore will not usurp the Court's role in explaining the law to the jury, but will assist the jury in determining whether Bayer acted as a reasonably prudent pharmaceutical manufacturer.") (internal quotations omitted) (citing *Wells*, 2013 WL 7208221, at *1; *In re Yasmin*, 2011 WL 6302287, at *25; *In re Fosamax Prods. Liab. Litig.*, 645 F.Supp.2d at 191; *see also In re Bard IVC Filters*, 2017 WL 6523833, at *8 (expert permitted to offer opinions concerning the FDA regulatory process and drug-maker's compliance). Dr. Kessler's relevant experience with FDA—he led the agency and he continues to advise companies regarding FDA regulatory compliance—makes him eminently qualified to testify as to the state law duty of care for drug makers:

> Moreover, as the Commissioner of the FDA, Dr. Kessler enforced the FDCA that applied to drug companies' conduct throughout the country. He received a law degree from the University of Chicago and has taught food and drug law at

[35] *Id.* at 132-34 (¶144-48); *Id.* at 142-43 (¶161-164).

> Columbia University Law School, as well as written "amicus briefs on the "interaction between State and federal law." Furthermore, he advises drug companies on how to meet their legal obligations. While Dr. Kessler has never sat for the bar exam and is not licensed to practice law in any particular state, his past experience qualifies him to testify about a drug company's duty of care under state law.

*In re Yasmin*, 2011 WL 6302287, at *14.

Further, experts may permissibly provide an expert opinion "that embraces an ultimate issue, to the extent that it may be relevant and assist the jury," so long as specialized legal terminology is not invoked. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D.W.Va. 2013). As the Court in *In re C.R. Bard, Inc.* explained:

> Under Federal Rule of Evidence 704, "[a]n opinion is not objectionable just because it embraces an ultimate issue." … "The best way to determine whether opinion testimony contains legal conclusions, 'is to determine whether the terms used by the witness have a separate, distinct and specialized meaning in the law different from that present in the vernacular.' "… Thus, Dr. Kessler may not offer an expert opinion, for example, Bard's Avaulta products were "not reasonably safe" or that Bard "failed to warn." Dr. Kessler may, however, offer a more general expert opinion, using terms that do not have a separate, distinct, and specialized meaning in the law.

*Id.*; *see also Raley v. Hyundai Motor Co.*, No. CIV-08-0376-HE, 2010 WL 528420, at *3 (W.D. Okla. Feb. 11, 2010) ("As with plaintiff's other experts, Dr. Batzer will not be permitted to offer opinions which are essentially legal conclusions. For example, he will not be permitted to testify that defendants' [actions] constituted 'negligence.' ") If and where Dr. Kessler's conclusions may implicate state tort law, courts have determined such conclusions to be an appropriate "application of the facts, as he believes them to be, to the law as he understands it and as will be instructed by the [c]ourt." *In re Actos Prods. Liab Litig.*, MDL No. 6:11-md-2299. 2014 WL 120973 at *12 (W.D. La. Jan. 10, 2014).

Here, Plaintiffs anticipate offering Dr. Kessler to address the following areas: the FDA's regulatory scheme in general, FDA practices and procedures, the FDA's relationship with pharmaceutical companies, the standard of care for the pharmaceutical industry based on his

training and experience, and Defendants' compliance with FDA regulations and industry standards and impact thereof (including the facts from which the jury could infer intent and relevant, non-cumulative facts Dr. Kessler relied upon in forming his opinion). These are all areas about which Dr. Kessler has been routinely permitted to testify. *See, e.g., Drake,* 2014 WL 5392995, at *6; *Wells,* 2013 WL 7208221, at *1–2*; In re C.R. Bard, Inc.,* 948 F. Supp. 2d at 628-32; *Georges v. Novartis Pharm. Corp.,* No. CV 06–5207 SJO (VBKx), 2012 WL 9064768, at *9-10 (C.D. Cal. Nov. 2, 2012); *Fosamax,* 645 F. Supp. 2d. at 192. Notably, Dr. Kessler offered similar opinions in the litigation concerning the pharmaceutical drug AndroGel. The AndroGel defendants made similar challenges to those Defendants makes here. The MDL court (the U.S. District Court for the Northern District of Illinois) held that Dr. Kessler's opinions did not constitute impermissible legal conclusions. *Id.* Indeed, the court held that "[t]here is no *per se* rule barring expert testimony on matters of law. The field of FDA regulation of pharmaceutical products and marketing is highly complex, and a jury reasonably requires assistance to understand it … The ultimate conclusions a jury will have to draw are rooted in state law, not federal law. And Dr. Kessler's testimony does not cover the ultimate issues that the jury will decide; rather, it concerns off-label marketing and FDA regulations." *In re Testosterone Replacement Therapy Prod. Liab. Litig.*, 2017 WL 1836443, at *14–15.

Other courts have similarly agreed that Dr. Kessler's purported "legal conclusion" opinions are admissible. *See generally In re Bard IVC Filters*, 2017 WL 6523833, at *7 ("Dr. Kessler may, however, offer opinions concerning the FDA regulatory process and Bard's compliance with the process."); *Drake*, 2014 WL 5392995, at *6 (permitting Dr. Kessler to "testify about the FDA's regulatory scheme in general, FDA practices, and procedures, [the defendant's] compliance with FDA regulations, the FDA's relationship with pharmaceutical companies, and the standard of care for the pharmaceutical industry based on his training and experience."). Moreover, this is not a case like those cited by Defendants where an expert sought to offer legal opinions that would determine

the outcome of a case. (Defs.' Mot., Dkt. #1786-3 at 17 (citing *In re Prograf Antitrust Litig.*, No. 11-MD-02242, 2014 WL 7641156 (D. Mass. Dec. 23, 2014)). For example, the *Prograf* court was deciding an antitrust claim (obviously different issues than those presented here) and determined that Dr. Kessler could testify about the standard practice for petition certifications, but could not opine that the requested (not implemented) label change would have constituted fraud on the FDA. *In re Prograf Antitrust Litig.*, No. 11-MD-02242, 2014 WL 7641156 (D. Mass. Dec. 23, 2014). The crux of the ruling was that Dr. Kessler could not testify about what *would* have been legal or illegal, or the law of fraud "more generally." *Id.* at *2. Such opinions are not at issue here as Dr. Kessler's opinions focuses on Defendants' marketing of their opioid products, including whether they marketed and promoted these products in a misleading manner and for non-indicated, off-label uses.

**B. Dr. Kessler Does Not Seek to Offer Undisclosed Opinions**

In a bare-bones paragraph thrown in at the end of their motion, Defendants argue that Dr. Kessler offered at his deposition a previously undisclosed opinion regarding Johnson & Johnson/Janssen subsidiaries' Noramco and Tasmanian Alkaloids role in supplying oxycodone from their "super poppy" for use in various Defendants' opioid products at issue in this litigation.[36] In fact, Dr. Kessler's testimony shows that he was responding to questions with facts he was aware of from his review of internal company documents. When asked if his opinions regarding Janssen were limited to Nucynta and Duragesic, he answered that that was generally correct, but that Defendants' documents showed that their products were interconnected, and in particular Janssen's and Purdue's documents show that Janssen provided the raw material for oxycodone, and that those documents also showed that this Noramco "super poppy" enabled oxycodone to be sold to the extent it was.[37] This was almost a direct quote from the documents to which Dr. Kessler referred, which he brought

[36] Defs.' Mot., Dkt. #1786-3 at 19.

[37] David A. Kessler, M.D., Dep. (04/26/19), Dkt. # 1963-16 at 526 L10 to 527 L20.

to his deposition, are in the record, and were on his reliance lists.[38] Defendants had the opportunity to question Dr. Kessler on his testimony at his deposition, and no Defendant sought to reopen his deposition to question him further about it, belying Defendants' claim of prejudice. There is no basis to exclude an answer Dr. Kessler gave in response to Defendants' questions where the answer simply referred to facts stated in Defendants' own documents, as cited on his list of reliance materials.

## CONCLUSION

For the foregoing reasons, Defendants' Motion to Exclude the Testimony of Dr. Kessler and Prof. Perri should be denied.

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Respectfully submitted,

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[38] Kessler Dep., Dkt. # 1963-16, Ex. 27 (attached hereto as Exh. 1); Kessler Dep., Dkt. # 1963-15, Ex. 2, Supplemental List of Materials Considered (attached hereto as Exh. 2); Kessler Rep., Dkt. #2000-8 at Appendix C (Materials Considered).

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